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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Daniel Perlman, et al.
Title:	PREPARED FOODS CONTAINING TRIGLYCERIDE-RECRYSTALIZED NON-ESTERIFIED PHYTOSTEROLS
Appl. No.:	10/677,634
Filing Date:	10/01/2003
Examiner:	Carolyn A. Paden
Art Unit:	1761
Conf. No.:	4182

DECLARATION UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Daniel Perlman, am an inventor on the above-referenced application ('634 application,) and I hereby declare as follows:

1. I am a Senior Scientist with the Department of Physics, Brandeis University, Waltham, Massachusetts.

2. I have read the Office Action dated August 12, 2005, concerning the above-referenced patent application.

3. I have read PCT/CA00/01298, published as WO 01/32029, ('298 application) cited by the Examiner in the pending Office Action.

4. Based upon an understanding of the '298 application as provided in the '298 specification, the product and the process of the '298 application differ from those provided by the subject '634 application for the reasons that follow.

5. Regarding the method of the '298 application, the disclosed method requires according to Claim 1

> a) heating the phytosterols and/or phytostanols to form a molten material;
> b) heating the edible oil or fat;
> c) mixing the molten material with the heated edible oil or fat; and
> d) cooling the composition so formed.

('298 application, page 19, lines 4-7.) The '298 application further elaborates:

> The **key feature** of the method-invention as described herein is the heating of the phytosterols to form a molten material **prior to mixing** with the heated oil or fat. Generally, phytosterols/stanols may be heated to this molten condition at a temperature of from about 120 to 160 C, most preferably from about 135 to 145 C. Although the present invention is not so limited, the melting point of most phytosterols is about 138-140 C. In one embodiment, no additional material need be added to the molten phytosterol material. This molten material so formed is then added to oil or fat which has been previously heated to a temperature of from about 90 to 150 C, more preferably from about 100 to 120 C. The oil/fat "composition" comprising the molten phytosterols is then cooled to room temperature. The resultant product is an oil or fat in which the phytosterols are and remain **substantially completely dissolved** at room temperature.

('298 application, page 7, lines 1-12, emphasis added.) Thus, the '298 application provides a multi-step process wherein the phytosterol and oil or fat are heated separately prior to mixing, and that upon cooling the resulting product is an oil or fat in which the phytosterols are and remain substantially completely dissolved at room temperature.

6. In contrast, the process and product provided by the subject '634 application differ substantially from those of the '298 application. Specifically, in the process of the subject '634

application, the phytosterol and oil components are heated all together until dissolved, and then cooled together resulting in the formation of triglyceride-recrystalized non-esterified phytosterols (TRPs.) TRPs so formed are substantially insoluble at room temperature. Accordingly, the product of the '298 application, being "substantially completely dissolved at room temperature" as described in the '298 specification (*vide supra*), cannot be the same product as provided by the subject '634 application wherein the TRPs substantially precipitate upon cooling.

7. Additionally, claims of the subject '634 application also require subjecting the combined phytosterol-fat product to oxidation by, for example, heating and/or exposure to air, such as shelf life exposure. This exposure necessarily alters the originally produced composition, further distinguishing it from the product of the '298 application that has not been oxidized.

8. I have read PCT/FI99/00121, published as WO 99/43218, ('218 application) cited by the Examiner in the pending Office Action.

9. In my opinion, based upon experimental findings provided herewith and an understanding of the '218 application as provide in the specification thereof, the process and product of the '218 application differ from those provided by the subject '634 application.

10. I produced and tested the products resulting from the '218 application. The '218 application provides for heating and dissolution of the phytosterols in oil, cooling of the mixture to about 60 degrees C, and mixing the resultant in water, also at 60 degrees C. The resulting precipitate is NOT the mixed fat plus phytosterol complex (TRP) described by the subject '634 application (produced in the absence of water), but much finer microcrystals of relatively pure phytosterols. This conclusion is based on melting point determination. Whereas the TRP complex of the subject '634 application produced from combining 10% phytosterols and 90% corn oil has a melting temperature of 60-63 degrees C, the same ingredients combined and subjected to the water-dependent process of the '218 application produces a crystalline mass that

when heated, begins melting at 90-92 degrees C and has melted at 98 degrees C. The melting temperature of the complex produced according to the subject '634 application reflects the co-mingling of fat and phytosterol in the crystalline structure thereby lowering the melting temperature. Additionally, the microscopic appearance and physical structure of the soft mixed crystals produced by the method of the subject '634 application are substantially different from the tiny microcrystals produced using the method of the '218 application.

11. I hereby declare that all the statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements are so made punishable by fine or imprisonment, or both, under 18 U.S.C. § 101 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

November 9 2005
Date

Daniel Perlman